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J&J Vaginal Mesh Faces FDA Safety Panel as Number of Lawsuits Rise

By David Voreacos and Alex Nussbaum - Sep 7, 2011

Marci Sutin Levin says U.S. regulators failed her by not requiring extensive testing before allowing Johnson & Johnson (JNJ) to sell the type of surgical mesh implanted in her in 2007.

The U.S. Food and Drug Administration used an abbreviated process known as 510(k) to clear the mesh, which supports weakened muscles that can't hold a woman's pelvic organs in place. Levin, a 65-year-old New York marketing executive, endures pain so intense that she can't work, sleep through the night or have sex with her husband, she said. Levin said the endless pain hurts worse than natural childbirth.

"The pain of childbirth was finite, and you're delivering a child," Levin said in an interview. "This was very, very different. It's relentless, and it's untenable. And it doesn't lead to anything."

Levin filed one of about 270 lawsuits pending against J&J, based in New Brunswick, New Jersey. C.R. Bard Inc., of Murray Hill, New Jersey, and other mesh makers also face litigation around the U.S. About 75,000 women a year have the devices inserted vaginally to treat pelvic organs that bulge, or prolapse.

The FDA warned July 13 of a rise in injuries related to the mesh, and it said last month the devices should be reclassified from moderate risk to high risk, a change that would typically require new clinical data.

Two-Day Hearing

A panel of outside FDA advisers begins a two-day hearing tomorrow on whether transvaginal mesh for pelvic organ prolapse, or POP, is safe and effective, and whether makers must submit more safety data to keep their products on the market. The panel also will discuss mesh used for stress urinary incontinence.

The hearing comes as the FDA weighs a U.S. Institute of Medicine report in July urging it to scrap the 510(k) process for moderate-risk devices. The current system allows devices like the mesh implant to enter the market if manufacturers show they are "substantially equivalent" to others already for sale. The IOM said a new process should be devised that provides reasonable assurance of the safety and effectiveness of moderate-risk devices.

"The clinical effectiveness of surgical mesh for transvaginal repair of POP has not been demonstrated," said William Maisel, deputy director of the FDA Center for Devices and Radiological Health, in a telephone interview. "We believe proper studies would need to be done."

Boston Scientific

An industry working group disputes the FDA's suggestion that the devices should be reclassified. Its members include mesh makers J&J; Bard; Boston Scientific Corp. (BSX) of Natick, Massachusetts; and American Medical Systems, acquired in June by Endo Pharmaceuticals Holdings Inc. (ENDP) of Chadds Ford, Pennsylvania. The Advanced Medical Technology Association, the manufacturers' lobbying arm in Washington, is also a member.

The group believes that the use of mesh in transvaginal procedures for prolapsed organs is "safe and effective, that serious adverse events remain rare and it is a valuable treatment option for women," it wrote on Aug. 30 to the advisers. "Key to the successful treatment of POP with surgical mesh is appropriate patient selection and surgeon experience."

A spokesman for J&J, Matthew Johnson, declined comment on the litigation. Bard spokesman Scott Lowry declined to comment on about 190 lawsuits it faces over its Avaulta pelvic mesh.

Adam Slater, the New Jersey attorney who represents Levin and about 100 other women who have sued J&J or Bard in New Jersey state court, said the agency is "at an important crossroads" over how to protect patients.

'Utterly Failed'

"The 510(k) process utterly failed to protect the thousands of women who were implanted," Slater wrote to the advisers. "Now the FDA now has the opportunity to at least protect women on a going-forward basis."

While the advisory panel won't take any formal votes this week, the FDA will poll the panel of researchers and physicians on whether to reclassify the devices and gather thoughts on how to conduct clinical studies, said Karen Riley, an agency spokeswoman, in a telephone interview today. It's not clear yet when the FDA will make a final decision on the devices, she said.

The mesh devices should be recalled, said Slater, of the law firm Mazie Slater Katz & Freeman in Roseland, New Jersey. Public Citizen, a consumer advocacy group in Washington, made a similar call in a statement last month.

Studies to determine if devices reviewed under the 510(k) process are safe and effective are rare, the Institute of Medicine said last month. Levin said that process failed to detect risks posed by her mesh, made by J&J's Ethicon unit.

'Irrevocable'

"It wasn't carefully tried and tested before it was implanted into me," she said. "I was told that it was a real improvement, that this would be great and I would be back at work in two weeks. It was irrevocable, what they did to me."

The mesh under review supports pelvic floor tissues that weaken or stretch as women undergo childbirth and age, causing organs including the bladder, rectum or uterus to bulge into the vagina. More than 2 million women are diagnosed with the condition each year, according to the industry working group.

About 300,000 women in the U.S. had pelvic organ prolapse surgeries last year. Between 2008 and 2010, the FDA received 1,503 reports of injury, malfunction or death associated with the surgery, a five-fold increase over the previous three-year period. Injuries include infection, organ perforation, urinary problems and mesh erosion.

Abdominal Hernias

Surgeons began using mesh in the 1950s to repair abdominal hernias. In 1996, the FDA cleared the first mesh product for stress urinary incontinence, and in 2002, the agency cleared the first mesh device for prolapse.

An FDA review of 110 studies that examined mesh in 11,785 women showed 10 percent had erosion within 12 months. Seven deaths were also reported, including four due to medical complications not directly related to the mesh placement procedure, according to the FDA.

Dr. Clifford Wheeless, an emeritus associate gynecology professor at Johns Hopkins University School of Medicine, said he has long told colleagues that inserting mesh transvaginally is inherently unsafe.

"You can't take a mesh from Company A, put it through the contaminated vagina, implant it under the bladder, and not get a rejection or an abcess," Wheeless said. "There's so much of the FDA's time wasted on thinking that Mesh A is going to be better than Mesh B, and Mesh C will be better than Mesh B. They don't understand the basic science of foreign bodies."

A recall would be too extreme, said another pelvic surgeon, Andrew Sokol, an associate professor at Georgetown University School of Medicine in Washington. He helped conduct a clinical trial of transvaginal POP mesh that found a 15.6 percent erosion rate after three months. Still, he said that the devices have their benefits for some women.

"We do these surgeries all the time without risk," said Sokol. "Thousands and thousands of these surgeries are done without complications. The data is still emerging. It's easy to react but what needs to be done are good studies."

To contact the reporters on this story: David Voreacos in Newark, New Jersey, at dvoreacos@bloomberg.net; Alex Nussbaum in New York anussbaum1@bloomberg.net.

To contact the editors responsible for this story: Reg Gale at rgale5@bloomberg.net; Michael Hytha at mhytha@bloomberg.net.